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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,951

04/20/2006

Brian Anderton

0380-P03923US0

8723

110 7590 10/19/2011
DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

10/19/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/562,951	Applicant(s) ANDERTON ET AL.
	Examiner DAVID J. STEADMAN	Art Unit 1656

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 October 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 22,26,27,32,36,38,39,41,42 and 55.
Claim(s) withdrawn from consideration: 31,33-35,40,43-46,53 and 54.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). 10/6/11
13. ☐ Other: _____.

/DAVID J. STEADMAN/
Primary Examiner, Art Unit 1656

Continuation of 3. NOTE: In view of the amendment to claims 22 and 36 to limit the claimed methods to "consisting of" the recited method steps, entry of the amendment after final rejection, filed on 10/6/11, would require further consideration and search. For example, applicant's position is that the amendment to limit the methods of claims 22 and 36 to "consisting of" excludes additional kinases (instant remarks at p. 9, second paragraph) and further consideration is required to determine whether or not the claims also exclude other unrecited elements, including a source of phosphate for CK1 phosphorylation of tau. Further consideration is also required to determine whether or not the determining step (b) in claims 22 and 36 encompasses analysis of all fragments, i.e., all potential phosphorylation sites, of a full-length tau protein as disclosed in the specification's working examples, or is limited to determining the phosphorylation state of only those sites recited in the claims. Also, claim 36 limits the method to "consisting of" the recited method steps, yet claim 38 recites the method of claim 36, which "further comprises" at least one additional method step and as such it is unclear as to the scope of claim 36. Further, the claims have yet to be limited to "consisting of" the recited method steps and a new search of the prior art is required. Moreover, the claims encompass numerous phosphorylation sites other than the elected species of S289 that have yet to be searched in the prior art and examined on the merits. Thus, even assuming *arguendo* the claims are free of the prior art with respect to the elected species of S289, a new search would be required for all of the non-elected species of phosphorylation sites as recited in claims 22 and 36.

Continuation of 11. does NOT place the application in condition for allowance because: While the amendment after final rejection would appear to obviate the rejection under 35 U.S.C. 112, second paragraph, the rejection under 35 U.S.C. 103(a) based on the combination of Anderton, Singh1, Singh2, Graves, Vitek, and Litersky and further in view of Hasegawa or Zhu, and the double patenting rejections, the amendment has not been entered because, as noted above, entry of the amendment would require further consideration and search. In the interest of compact prosecution, it is noted that even assuming *arguendo* the amendment had been entered, the rejections under 35 U.S.C. 103(a) based on the combination of Anderton, Lau, Graves, Vitek, Hasegawa, and Yamamoto and further in view of Zhu would be maintained for the reasons of record. Applicant's arguments in the amendment filed on 10/6/11 have been fully considered. However, in view of the non-entry of the amendment, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Office action mailed on 7/6/11 for the reasons of record stated therein. In the interest of compact prosecution, applicant's applicable arguments have been addressed below.

Regarding the obviousness rejections, at p. 8 of the instant remarks, applicant expresses frustration with the examiner's prior rejections based on obviousness. Applicant argues many of the sites of tau phosphorylated by CK1 were unknown prior to the invention and the claims have been amended to require detection of these novel sites phosphorylated by CK1, rather than any and all phosphorylation sites on tau.

Applicant's argument is not found persuasive. At least for the reasons of record, the examiner maintains that the obviousness rejections set forth in the Office action mailed on 7/6/11 and establish a *prima facie* case of obviousness.

Beginning at p. 8 of the instant remarks, applicant argues the examiner's interpretation of the claims as encompassing an additional kinase in the method confounds the intended use of the method as stated in the preamble. According to applicant, the examiner is on record stating that a combination of kinases constitutes a separate and distinct invention.

Applicant's argument is not found persuasive. As noted in the prior Office action, there is no claim limitation that excludes a combination of kinases in the claims. Moreover, claim 33, which depends from claim 22 and is currently withdrawn, indicates that applicant's claimed method is intended to encompass a combination of kinases. Contrary to applicant's position, while the examiner is on record as stating the inventions do not share a special technical feature, the examiner is not on record as stating that a combination of kinases constitutes a separate and distinct invention.

At p. 9 of the instant remarks, applicant argues the amendment to recite "consisting of" precludes the examiner's erroneous interpretation of a combination of kinases and does not require further consideration and search. According to applicant, this amendment is necessitated by the examiner's insistence that the claims encompass a combination of kinases, which is in error as this confounds the objective of the claim.

Applicant's argument is not found persuasive. The examiner's interpretation of the claims filed on 4/18/11 as encompassing additional kinases is fully consistent with the specification and the claims (see, e.g., claims 33-35) and the amendment requires further consideration and search at least for the reasons set forth above.

The information disclosure statement (IDS) filed on 10/6/11 is acknowledged. According to MPEP 609.01 and 37 CFR 1.97(d), an IDS filed after final rejection shall be considered by the Office is accompanied by a 1.97(e) statement and the 1.17(p) fee. According to 37 CFR 1.97(e), "A statement under this section must state either:

- (1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- (2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement."

In reviewing the IDS for the 1.17(p) fee, it is noted that the 1.17(p) fee has been submitted. In reviewing the IDS for a 1.97(e) certification statement, it is noted that while a statement that "Each item of information contained in the instant IDS was first cited in an Official Action issued connection with the corresponding Japanese application", the examiner cannot find a certification statement in accordance with 1.97(e) as noted above. The information disclosure statement filed 10/6/11 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.